

U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE
FISCAL YEAR 2008 CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES
QUALITY ASSURANCE AUDIT 2008-1

OBSERVATION AUDIT REPORT NO. OAR-08-01

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Enclosure

1.0 INTRODUCTION

The Center for Nuclear Waste Regulatory Analyses (CNWRA) provides technical support to the U.S. Nuclear Regulatory Commission (NRC) staff under NRC Contract NRC-02-07-006. Under this contract, CNWRA is required to meet the quality assurance (QA) requirements of 10 CFR Part 63. On April 14-18, 2008, QA and technical staff from Southwest Research Institute (SwRI) and the University of Texas San Antonio (auditors) conducted the Fiscal Year 2008 CNWRA, Geosciences and Engineering Division (GED), QA Audit 2008-1 at CNWRA facilities in San Antonio, Texas. NRC staff from the Office of Nuclear Material Safety and Safeguards (observers) observed the CNWRA audit.

The objective of this audit was to evaluate the CNWRA QA program to verify that it met applicable requirements and was being effectively implemented. The objective of the observers was to evaluate the effectiveness of the audit process and the implementation of the QA program.

Details of the scope, conduct, findings, and conclusion of the audit are available in the May 16, 2008, CNWRA report, Quality Assurance Audit Report for Geosciences and Engineering Division Audit 2008-1 of NRC-Funded Programs Conducted by the Center for Nuclear Waste Regulatory Analyses. (ML081370559)

2.0 MANAGEMENT SUMMARY

The audit team comprised qualified SwRI auditors and technical specialists trained by CNWRA in auditing techniques. The observers found the auditors to be independent of the activities and technical areas being audited. The auditors identified six nonconformances with QA program requirements, five of which were corrected during the course of the audit, nine recommendations to improve implementation of the QA program, and five good practices. The auditors determined that the six identified nonconformances are unlikely to have an adverse impact on the quality of CNWRA technical products. The auditors concluded that the CNWRA QA program was being effectively implemented and provided adequate controls over technical product development.

The observers determined that the auditors achieved their objective. The audit was effective in verifying compliance with procedural controls in the areas examined and that the CNWRA QA program was being implemented adequately. The observers also determined that the technical adequacy of the work products and procedures used to govern and control work was satisfactory. The observers agreed with the auditors' conclusions that the CNWRA has effectively implemented its QA program.

The observers noted that the implementation of the CNWRA QA program has improved over recent years. The observers have seen improvements in areas such as attention to detail, completion and control of scientific notebooks, utilization of the QA trend program, and conduct of surveillances. The observers recommended that CNWRA management and staff maintain their focus on attention to detail and continuing improvement.

3.0 PARTICIPANTS

3.1 Auditors

Christopher Hobson	Audit Team Leader, Institute Quality Systems (IQS)
Thomas Trbovich	QA Auditor, IQS
Donald Dunavant	QA Auditor, IQS
Julie Garcia	QA Auditor, IQS
Dr. Richard Page	Technical Specialist, Materials Science, SwRI
Robert Morgan	Technical Specialist, Software, SwRI
Dr. Alan Dutton	Technical Specialist, Aqueous Geochemistry, Hydrogeology, University of Texas San Antonio

3.2 NRC Observers

Frank Jacobs	Observation Team Leader
Christopher Markley	Technical Specialist
Hipolito Gonzalez	Technical Specialist
Deborah DeMarco	NRC Center Deputy Program Manager

4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION

The CNWRA provides technical support to NRC staff under NRC Contract NRC-02-07-006. In performing work under this contract, CNWRA must meet the QA requirements of 10 CFR Part 63. The CNWRA conducted the annual audit to determine whether its QA program is effectively implemented. NRC staff observed the conduct of the QA audit to determine the adequacy of the audit process and the effectiveness of the QA program implementation. The auditors performed the audit following CNWRA Quality Assurance Procedure (QAP)-011, "Audits," and NRC staff observed the audit using the guidance of NRC Manual Chapter 2410, "Conduct of Observation Audits."

5.0 SCOPE OF AUDIT

The scope of this performance-based audit was to determine whether the CNWRA QA program meets 10 CFR Part 63 QA requirements and is being effectively implemented for NRC-sponsored technical activities. The audit evaluated programmatic requirements and the corrective action process to determine effectiveness.

6.0 CONDUCT AND TIMING OF THE AUDIT

The observers determined that the audit scope was achieved. The observers determined that the auditors were thorough, effective, and performed in a professional manner. The observers determined that the timing, length, and application of resources to complete this annual CNWRA QA audit were appropriate for the current level and type of activities.

7.0 AUDIT TEAM QUALIFICATION AND INDEPENDENCE

The audit team comprised an Audit Team Leader, three QA auditors, and three technical specialists. The observers found the qualifications of the Audit Team Leader and QA auditors to be acceptable and in compliance with the CNWRA QA program. The observers also found

the audit team technical specialists to be qualified through training and experience. The QA auditors and technical specialists were independent of the activities they reviewed.

8.0 AREAS OF EXAMINATION AND RESULTS

8.1 QA Elements

The auditors evaluated the following QA programmatic elements:

<u>QA Programmatic Elements</u>	<u>Corresponding GED QA Manual Chapter</u>
Organization	1
QA Program	2
Design Control	*
Scientific Engineering Investigation and Analysis Control	3
Procurement Document Control	4
Instructions, Drawings, and Procedures	5
Document Control	6
Procurement Control	7
Identification and Control of Items, Software, and Samples	8
Control of Processes	9
Inspection	10
Test Control	11
Control of Measuring and Test Equipment	12
Handling, Storage, and Shipping	13
Inspection and Test Status	14
Nonconformance Control	15
Corrective Action	16
Records Control	17
Audits	18

*CNWRA does not perform design-related activities.

Given the limited technical topics chosen for the audit, a comprehensive approach was used by the audit team to evaluate the QA programmatic elements. In addition to evaluation of applicable programmatic elements during each technical session, each auditor was assigned four projects to verify that programmatic requirements had been implemented, using a QA checklist as the criteria. For those elements that were not likely to be adequately covered in the technical sessions or project reviews, specific topics such as nonconformance control, document control, and purchasing, were assigned to the auditors.

The auditors reviewed and evaluated material and documentation related to the QA programmatic elements and interviewed responsible CNWRA personnel to determine the effectiveness of implementing procedures and technical processes. Details of the scope, conduct, findings, and conclusion of the audit are available in the May 16, 2008, CNWRA Audit Report.

8.2 Technical Activities

CNWRA management applied a risk-informed approach in selecting technical activities to be evaluated during the CNWRA QA program audit. Technical and programmatic risks and the

time since the previous audit of an activity were considered in selecting the areas for the audit. The auditors evaluated the following technical activities:

- Climate and Infiltration
- Coating Debris Source Term for Pressurized Water Reactor (PWR) Loss-of-Coolant Accident (LOCA)
- BDOSE Software Development

The auditors used a performance-based approach to evaluate the effectiveness of the QA program by interviewing technical personnel responsible for the development of technical products, evaluating selected scientific activities, assessing products, and analyzing documentation supporting the underlying engineering and scientific processes for compliance with associated procedural requirements. Details of the scope, conduct, findings, and conclusion of the audit are available in the May 16, 2008, CNWRA Audit Report.

The auditors evaluated the qualifications of personnel performing technical work in the areas reviewed by reviewing training, education, and experience records of personnel who conducted scientific studies. The auditors concluded that the technical personnel reviewed were qualified for the work they performed and their qualification records supported their individual position descriptions.

8.3 Results

The auditors identified the following nonconformances with QA program requirements and determined that they are minor in significance and unlikely to have an adverse impact on the quality of CNWRA technical products:

1. Technical Operating Procedure (TOP)-012, "Identification and Control of Samples, Chemical Reagents and Standards," defines specific requirements for controlling samples. The following discrepancies were identified in the control of natural geological samples in Building 51: no unique sample identification code for one sample and four subsamples; Sample Custody/Control Log was not available for 29 samples; Sample Custody/Control Log created for 14 samples was missing required fields, including date of receipt, date of entry into log, person making entry, and storage location; and Sample Custody/Control Log was not updated after subsample BB3-16 was taken from sample BB3.
2. QAP-001, "Scientific Notebook Control," defines specific requirements for documentation in each scientific notebook (SN). The following discrepancies were identified for SN 891E that did not conform to these requirements: no record of person making entries; information was not marked as proprietary, when required; pages were not numbered; and confirmatory calculations included in the SN were not complete. (Nonconformances corrected during the audit.)
3. Documentation errors were identified that did not conform to QAP requirements. On Form QAP-6, "Document Review Request and Transmittal Control," a correction was made, but was not initialed and dated, as required by QAP-012, "Quality Assurance Records Control." On Form QAP-3, "Report Review/Comment Resolution Record," the reviewer did not sign and date Response Accepted By on pages 1-2, as required by QAP-002, "Review of Documents, Reports, and Papers." (Nonconformances corrected during the audit.)

4. QAP-004, "Surveillance Control," requires the surveillance schedule to be revised as necessary. A software development surveillance scheduled for January 2008 was not conducted, rescheduled, or justified. A memo was prepared and dated 4/16/2008 stating the surveillance was not necessary as a result of limited activity and other surveillances planned for FY08. (Nonconformances corrected during the audit.)
5. Several bottles of expired reagents and undated reference material, and two bottles of iron sulfate and ferric sulfate which could not be traced to purchase and verified as being from ASL supplier, were not disposed of as required by TOP-012, "Identification and Control of Samples, Chemical Reagents and Standards." (Nonconformances corrected during the audit.)
6. Documentation errors were identified in the review of "Technical Assistance to the Division of Spent Fuel Storage and Transportation for Transportation Aging and Disposal Canister Designs (TAD Design)." On Form QAP-012, "Instructions to Technical Reviewers," two boxes for Software Control and Calculation Verification were not initialed as completed, as required by QAP-012, "Quality Assurance Records Control." On Form QAP-6, "Document Review Request and Transmittal Control," QA review of QAP-002 requirements was noted as NA, when review is required by QAP-002, "Review of Documents, Reports, and Papers." (Nonconformances corrected during the audit.)

The auditors identified the following QA program implementation improvement recommendations:

1. GED should implement an electronic smart form for QAP-3, "Report Review/Comment Resolution Record," to increase efficiency and clarity of record.
2. "First Draft Report: Infiltration Tabulator for Yucca Mountain: Bases and Confirmation Section on Analysis and Codes," identifies a nonvalidated code KINEROSZ as being used to generate results; other codes identified have been validated. Recommend separating codes and identifying other wording to indicate results are preliminary or intermediate.
3. An Incorporation or Completion Check Box should be added to QAP-3, "Report Review/Comment Resolution Record," as a method for verifying that each comment has been incorporated in the revised document.
4. TOP-018, "Development and Control of Scientific and Engineering Software," should be revised in the following areas to provide guidance for applications similar to BDOSE: description of code documentation; individual runs of software; test case run procedure; configuration control; and remove quarterly surveillance requirement, as the practice has changed. These areas are limited in TOP-018 and do not cover all situations.
5. In recognition of the transition from classical scientific experiments and engineering testing toward the review of documents by others, CNWRA should review the process for documenting activities to decide if further guidance is warranted.

6. An inventory should be conducted of all chemicals in storage cabinets located in Building 57 in order to dispose of unnecessary and expired chemicals, reagents, and reference material.
7. A discussion was held with division senior management concerning the descriptions contained within the QA Manual (QAM) and NUREG/BR-0240, Reporting Safety Concerns to the NRC (identified as AP-0240), regarding how allegations against quality are to be investigated and reported. The QAM states that allegations will be investigated by the Division Vice President and a determination then made by him to report to the NRC. NUREG/BR-0240 states that allegations should be directly reported to the NRC with as much information as possible requested from the person presenting the allegation. This guidance implies that no internal investigation is to be conducted. Both documents should be reviewed and a determination made which process will be followed; the QAM and NUREG/BR-0240 should identify the same process.
8. Several changes or corrections to comments and responses were noted on Form QAP-3, "Report Review/Comment Resolution Record," that were not initialed and dated; the process for initialing and dating corrections should be implemented in all cases.
9. More emphasis should be placed on the generation, review, and approval of the Quality Requirements Application Matrix (QRAM) and to accurately indicate only those QA elements that are appropriate for the project. In a number of cases, several QA procedures were identified that were not applicable to the project. The QRAM reviewed for 3DStress®, signed off and approved in October 2007, indicates software modification, although no modification was ever intended to take place.

The auditors identified the following good practices:

1. The Climate and Infiltration team working on the Infiltration Tabulator for Yucca Mountain (ITYM) code was well-integrated into the TPA effort, and, as a result, the transfer of study results from ITYM to the next upgrade of TPA input is expected to be well-coordinated.
2. Two scientific notebooks reviewed during the audit (SN 563E and SN 783) were very thorough, detailed, and complete.
3. The BDOSE product was very user friendly, and changes incorporated resulted in much greater functionality.
4. All required measuring and test equipment was calibrated, current, and properly labeled, and equipment required to be verified before use was meticulously documented in scientific notebooks to ensure the equipment is adequate for use.
5. "FLUENT 6.3 Software Validation Report," dated 1/8/2008, was very thorough, detailed, and complete.

9.0 NRC STAFF FINDINGS/CONCLUSIONS

The NRC observers concluded the audit process was well planned, thorough, effective, and performed in a professional manner. Audit checklists developed and used by the auditors were

comprehensive and effective in providing guidance to the auditors. The Audit Team Leader provided ample opportunities for the observers to provide comments and ask questions throughout the audit process. The auditors and observers discussed potential findings with CNWRA management during daily caucuses, audit debriefs, and at the post-audit conference.

The observers determined that CNWRA Audit 2008-1 achieved its objectives of evaluating the CNWRA QA program to verify that it met applicable requirements and was being effectively implemented. NRC observers determined that the CNWRA audit was effective in reviewing, evaluating, and determining risks and the associated compliance with procedural requirements in the areas controlled by QA program requirements. NRC observers agreed with the auditors' conclusions that the CNWRA QA program was being effectively implemented and provided adequate controls over technical product development.

The observers noted that the implementation of the CNWRA QA program has improved over recent years. The observers have seen improvements in areas such as attention to detail, completion and control of scientific notebooks, utilization of the QA trend program, and conduct of surveillances. The observers recommended that CNWRA management and staff maintain their focus on attention to detail and continuing improvement.